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| 09/770,102 | 01/25/2001 | Roger Craig | 10069/1062 | 5353 |

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EXAMINER

COUNTS, GARY W

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,102

Applicant(s)

CRAIG, ROGER

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-13, 27, 28, 30, 32-52 and 55-80 is/are pending in the application.
- 4a) Of the above claim(s) 35-50 and 55-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-13, 27, 28, 32-34, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

The amendment filed October 29, 2004 is acknowledged and has been entered. New claims 79 and 80 have been added. Currently claims 1-5, 7-13, 27, 28 30, 32-52, 55-80 are pending. Claims 35-50, 55-80 are withdrawn.

Rejections withdrawn

The rejection of claims 1 and 51 as being incomplete for omitting essential steps is withdrawn in view of amendments to the claims and Applicant's arguments.

The rejection of claims of claim 1 as being vague and indefinite with respect to the recitation "correspond" and also to the moiety in the mixture is withdrawn in view of amendments to the claims and Applicant's arguments.

The rejections of claims 5 and 12 as being vague and indefinite is withdrawn in view of Applicant's arguments.

The rejections of claims 1-4, 7, 9-11, 13, 28 and 32-34 as being anticipated by Heroux et al is withdrawn in view of amendments to the claims and Applicant's arguments.

The rejection of claims 8, 27, 30, 51 and 52 as being obvious is withdrawn in view of amendments to the claims and Applicant's arguments.

Election/Restrictions

1. With respect to the traversal of Claims 77 and 78 in the reply filed on October 29, 2004 is acknowledged. The traversal is on the ground(s) that that detecting dissociation requires the same steps as detecting association and that a search for art related to

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association of polypeptides will yield art on dissociation, and therefore it would not pose a serious burden on the examiner. This is not found persuasive because of reasons of record and further, in order to detect the dissociation of the binding partner polypeptides, the binding partner polypeptides would have to already be bound to the tagged polypeptide and this binding confirmed and then steps of detection to see if the binding partner polypeptide is dissociated from the tagged polypeptide. Therefore, detection of dissociation requires step which are not required in detection of association. Further, while the searches would be expected to overlap there, is no reason to expect the searches to be coextensive.

The requirement is still deemed proper and is therefore made FINAL.

2. Newly submitted claims 79 and 80 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Newly submitted claims 79 and 80 recite, "wherein addition or removal of said moiety promotes association of said one or more binding partner". According to the specification on page 18, lines 15-18 the term associates is equivalent to the term binds. Therefore, binding of the binding partner to the tagged polypeptide is required. Claims 79 and 80 further recite "from the corresponding one or more tagged binding partner polypeptides". This recitation contradicts the recitation of "association". Therefore, the Examiner has interpreted the claim to be for dissociation of the binding partner from the tagged polypeptide and as stated in the previous office action and above this method is independent and distinct from the invention originally claimed.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 79 and 80 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

3. Claim 1 is objected to because of the following informalities: Claim 1, part (B) the recitation " of a said tagged binding partner polypeptide" should be --of said tagged binding partner polypeptides--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-5, 7-13, 27, 28, 30, 32-34, 51 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 51 are vague and indefinite because it is unclear how applicant can detect binding between the tagged binding partner polypeptides and the binding partner polypeptides by the addition of the detector molecule. The detector molecule as recited binds to the tagged binding partner and regardless if the tagged binding partner binds to the binding partner polypeptide or not the detector molecule will bind to the tagged binding partner and thus a positive signal will always be detected. Claims 1 and 51 as instantly recited will not work.

Allowable Subject Matter

6. Claims 1 and 51 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Response to Arguments

7. Applicant's arguments filed October 29 2004 have been fully considered but they are not persuasive.

With respect to the 112 2nd rejection above, In the remarks section of the amendment filed October 29, 2004 the Applicant appears to combine this 112 2nd rejection with the 112 2nd rejection of the omitting essential steps.

Applicant argues that the specification describes, embodiments in which FRET or FCS are used to detect association. Applicant directs Examiners attention to various portions of the specification concerning FRET. Particularly, (p. 9 line 19-p. 10 line 2), (p. 21, line 17-p. 22 line 3), (p. 77, line 24-p. 78, line 4) and (p. 96, line 18-p. 98, line 12). This is not found persuasive because the claim in and of itself does not make clear how detection of the binding between the tagged binding partner polypeptides and the binding partner polypeptides is achieved. With regards to the FRET assays Applicant has directed to Examiner Attention. Even if the method of claim 1 is perform as a FRET assay the claim is still vague and indefinite because the binding between the tagged polypeptide and the detector molecule with the reporter will be detected and regardless if binding has occurred between the binding partner polypeptide and the tagged binding partner polypeptide has occurred there will be a positive signal and as such one could

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not distinguish if binding has occurred or not. With respect to the argument of FCS Applicant argues that FCS can be performed with a single labeled species. Once again, the claims recite that the detector molecule binds to the tagged binding partner and regardless if the tagged binding partner binds the binding partner polypeptide or not the detector molecule will bind to the tagged binding partner and a positive detection would occur.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

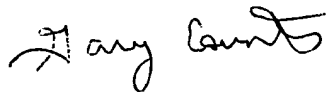
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
Art Unit 1641
December 22, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
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12/04/05